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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,416	05/09/2001	Chaitan Khosla	300622000501	5252

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EXAMINER

PONNALURI, PADMASHRI

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 04/17/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/852,416

Applicant(s)

Khosla et al

Examiner

Padmashri Ponnaluri

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 28, 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-60 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☒ Other: Restriction Fax cover sheet

Art Unit: 1639

DETAILED ACTION

1. Claims 1-60 are currently pending in this application.
2. The preliminary amendment filed on 5/9/01, and the preliminary amendment file don 9/28/01 have been considered and entered into the application.
3. New claims 29-58 have added by the amendment filed on 5/9/01; and new claims 59-60 have been added by the amendment filed on 9/28/01.

Please Note: In an effort to enhance communication with our customers and reduce processing time, a dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Andrew Wang, Supervisory Patent Examiner at andrew.wang@uspto.gov or 7(703)306-3217. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restriction

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Art Unit: 1639

- I. Claims 1-4, drawn to a method to prepare a nucleic acid with a nucleic acid encoding modified PKS form of a nucleotide sequence encoding a naturally occurring modular PKS, classified in class 435, subclass 69.2.
- II. Claim 5, drawn to a nucleic acid comprising a nucleotide sequence encoding a modified PKS, classified in class 536, subclass 23.1.
- III. Claims 6-7, drawn to a cell culture modified to contain the nucleic acid, and the method to prepare a polyketide, classified in class 435, subclass 70.1.
- IV. Claim 8, drawn to a novel polyketide, classified in class 536, subclass 23.1.
- V. Claims 9, drawn to a method to an antibiotic, classified in class X, subclass X.
- VI. Claim 10, drawn to an antibiotic prepared by the method of claim 8, classified in class 536, subclass 7.2.
- VII. Claims 11-12, drawn to a method to construct a library of colonies containing expression vectors for a multiplicity of different polyketide synthases, classified in class 435, subclass 320.1.
- VIII. Claims 13-14, 17-18, drawn to a multiplicity of cell colonies, classified in class 435, subclass 70.1.
- IX. Claim 15, 19, drawn to a method to produce a library of modular PKS proteins, classified in class 435, subclass DIG. 46.
- X. Claims 16, 20 drawn to a library of PKS proteins, classified in class 435, subclass DIG. 35.

Art Unit: 1639

- XI. Claims 21-22, drawn to a multiplicity of polyketides, classified in class 536, subclass 7.2.
- XII. Claim 23, drawn to a method to identify a successful candidate polyketide, classified in class 435, subclass 6.
- XIII. Claims 24 (in-part), drawn to a compound of formula 1, classified in class 549, subclass 266.
- XIV. Claim 24 (in-part), drawn to a compound of formula 2, classified in class 549, subclass 200.
- XV. Claim 24 (in-part), drawn to a compound of formula 3, classified in class 549, subclass 249.
- XVI. Claim 24 (in-part), drawn to a compound of formula 4, classified in class 549, subclass 249.
- XVII. Claim 24 (in-part), drawn to a compound of formula 7, classified in class 549, subclass X.
- XVIII. Claim 24 (in-part), drawn to a compound of the formula 8, classified in class X, subclass 335.
- XIX.. Claims 25-26, drawn to a compound of formula 5, classified in class 549, subclass 249.
- XX. Claims 27-28, drawn to a compound of formula 6, classified in class 549, subclass 263.

Art Unit: 1639

- XXI. Claims 29-55 and 58, drawn to a compound of given formula, classified in class 549, subclass 263.
- XXII. Claim 56, drawn to a compound, classified in class 549, subclass 263.
- XXIII. Claim 57, drawn to a compound 6-desmethyl-6-ethylerythromycin A, classified in class 549, subclass 263.
- XXIV. Claim 59, drawn to a compound of formula, classified in class 549, subclass 263.
- XXV. Claim 60, drawn to a compound of the formula, classified in class 549, subclass 263.

(NOTE that the claims 56-60 may be joined with claims 29-55 if the elected species would read on the compounds.)

5. The inventions are distinct, each from the other because of the following reasons:
- a). Inventions III and IV; V and VI; IX and X are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the different products can be prepared using other known methods such as solid phase synthesis.

Art Unit: 1639

b). Inventions of groups II, IV, VI, XI, XIII, XXIII- XXV are all drawn to different products. These distinct products are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Thus, restriction between the compounds is proper.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Even though some of the groups are classified in the same class/subclass, this has no effect on the non-patent literature search. Different inventions or groups would require completely different searches in non-patent databases, and there is no exception that the searches would be co-extensive. Therefore, these do not create an undue search burden, and restriction for examination purposes as indicated is proper.

7. This application contains claims directed to the following patentably distinct species of the claimed invention: Depending on the elected group applicants are requested to elect a single species for each of the following:

- A) If group I is elected, applicants are requested to elect a single species of the following,
 - a) method of modification (i.e., deleting, or inactivating or replacing);
 - b) number of first regions;
 - c) extender unit;

Art Unit: 1639

d) chain length of polyketide.

B) If group II is elected, applicants are requested to elect a single nucleotide sequence which encodes a modified PKS.

C) If group III is elected, applicants are requested to elect a single nucleotide sequence which encodes a modified PKS.

D) If group VII is elected, applicants are requested to elect a single nucleotide sequence which encodes a modified PKS.

E) If group VIII is elected, applicants are requested to elect a single nucleotide sequence encoding a modular PKS.

F) If group XI is elected, applicants are requested to elect a single combination of polyketides (i.e., as in claim 22); and the length of the polyketide in each library.

G) if group XIII is elected, applicants are requested to a single species for each of the following:

I) a single species representing X^1 ;

ii) a single species representing R^1 and R^2 ;

H) If group XIV is elected, applicants are requested to elect a single species for each of the following:

I) a single species representing R^1 , R^2 , and R^3 ;

ii) a single species representing X^1 and X^2 .

I) If group XV is elected, applicants are requested to elect a single species for each of the following:

Art Unit: 1639

I) a single species representing R^1 , R^2 , R^3 ;

ii) a single species representing X^1 , X^2 and X^3 .

J) If group XVI is elected, applicants are requested to elect a single species for each of the following:

I) a single species representing R^1 , R^2 , and R^3 ;

ii) a single species representing X^* and X^2 .

K) If group XVII is elected, applicants are requested to elect a single species for each of the following:

I) a single species representing R^1 to R^5 ;

ii) a single species representing X^1 and X^3 and X^6 ;

L) If group XVIII is elected, applicants are requested to elect a single species for each of the following:

I) a single species representing R^1 to R^5 ;

ii) a single species representing X^2 ;

iii) a single species representing each X^1 and X^3 and X^4 and X^5 .

M) If group XIX (claims 25-26) is elected, applicants are requested to elect a single species for each of the following:

I) a single species representing R^1 to R^5 ;

ii) a single species representing each X^1 to X^5 .

Art Unit: 1639

N) If group XX (claims 27-28) is elected, applicants are requested to elect a single species for each of the following:

- I) a single species representing R^1 to R^6 ;
- ii) a single species representing each X^1 to X^5 .

O) If group XXI (claims 29-55) is elected, applicants are requested to elect a single species for each of the following:

- I) a single species representing each of the R_1 to R_6
- ii) a single species representing Q;
- iii) a single species representing each of the L_1 to L_4 ;
- iv) a single compound from claims 53-55 which represents the elected groups of R_1 to R_6 , Q; and L_1 to L_4 .

P) If group XXIV (claim 59) is elected, applicants are requested to elect a single species for each of the following:

- I) a single species representing each of the R_1 to R_6
- ii) a single species representing Q;
- iii) a single species representing each of the L_1 to L_4 .

Q) If group XXV (claim 60) is elected, applicants are requested to elect a single species for each of the following:

- I) a single species representing each of the R_1 to R_6
- ii) a single species representing Q;

Art Unit: 1639

iii) a single species representing each of the L_1 to L_4 .

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

For this response to be complete and for search purposes, applicants should provide the chemical structure of elected compounds (or species) and name of the elected compound, wherein each specific formula substituents of each of the above identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CAR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

Art Unit: 1639

be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CAR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CAR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a request under 37 CAR 1.48(b) and by the fee required under 37 CAR 1.17(I).

10. Applicant is required to reply to this restriction requirement within 30 days of mailing this action. See MPEP 809.2(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner is on *Increased Flex Schedule* and can normally be reached on Monday to Friday from 7.00 AM to 3.30 PM.

Art Unit: 1639

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

P. Ponnaluri
Primary Examiner
Technology Center 1600
Art Unit 1639
09 April 2003


PADMASIRI PONNALURI
PRIMARY EXAMINER



RESTRICTION ELECTION FACSIMILE TRANSMISSION

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TO EXAMINER: **P. Ponnaluri**

ART UNIT: **1639**

SERIAL NUMBER: 09/852,416

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